Cue Biopharma to Present at the Federation of Clinical Immunology Societies (FOCIS) 2023 Annual Meeting

June 14, 2023

BOSTON, June 14, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body, announced today that it will deliver an oral presentation on its Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* platform and biologics as well as a poster on the company's bispecific protein, CUE-401, for the treatment of autoimmune and inflammatory diseases at the Federation of Clinical Immunology Societies (FOCIS) 2023 Annual Meeting, being held June 20-23, 2023 in Boston, Massachusetts.

Presentation Details

Oral Presentation

Session: Immuno-oncology and Cell Therapy
Title: Immuno-STAT Platform: TCR-selective Engagers for Selective Targeting of IL-2 to Tumor-Specific T Cells
Presenter: Steven Quayle, Ph.D., vice president and head of Research Biology & Translational Medicine, Cue Biopharma
Date and Time: Wednesday, June 21, 2023, 4:45 p.m. – 5:00 p.m. EDT

Dr. Quayle will describe the company's CUE-100 series of Immuno-STAT biologics, designed to enable selective targeting of the immunostimulant cytokine interleukin-2 (IL-2) to tumor specific T cells for enhanced efficacy and safety profiles. Proof of concept for this platform has been achieved with clinical data from CUE-101, the company's lead candidate. The data has demonstrated anti-cancer efficacy with a favorable tolerability profile and supports potential registrational paths for both CUE-101 as a monotherapy in third line (3L) recurrent/metastatic (R/M) human papillomavirus (HPV)16+ head and neck squamous cell carcinoma (HNSCC), and CUE-101 in combination with KEYTRUDA® (pembrolizumab) in first line (1L) R/M HPV16+ HNSCC. Additionally, Dr. Quayle will discuss the modularity of the Immuno-STAT platform, which has enabled rapid generation of additional Immuno-STAT candidates targeting other tumor antigens, such as mutated KRAS or Wilms' Tumor 1 (WT1). This includes Cue Biopharma's second CUE-100 series candidate, CUE-102, that is being evaluated in a Phase 1 trial for the treatment of WT1 positive malignancies. Taken together, the clinical de-risking achieved with CUE-101 supports broad applications of the Immuno-STAT platform to target diverse cancers.

Poster Presentation

Session: Exhibit & Poster Opening Reception
Title: CUE-401: A Novel IL-2/TGF-beta Fusion Protein for the Induction of CD4+ FOXP3+ Regulatory T Cells
Presenter: Rich DiPaolo, Ph.D., Professor and Chair, Saint Louis University, High Ridge, Missouri, U.S.
Date and Time: Tuesday, June 20, 2023, 6:00 p.m. – 7:45 p.m. EDT

Cue Biopharma's collaborator, Dr. DiPaolo, will discuss *in vitro* and *in vivo* data demonstrating the potential of CUE-401, the company's novel bispecific protein designed to induce and expand regulatory T cells (Tregs) for the treatment of T-cell mediated autoimmune and inflammatory diseases. The ability of CUE-401 to effectively induce de novo FOXP3-expressing iTregs from both mouse and human CD4+ T cells – while also expanding existing Tregs – and suppress autoimmune inflammation represents a novel therapeutic approach.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-MHC (pMHC) molecules along with rationally engineered IL-2 molecules. This singular biologic is anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient's body. The binding affinity of IL-2 for its receptor has been deliberately attenuated to achieve preferential selective activation of tumor-specific effector T cells while reducing the potential for effects on regulatory T cells (Tregs) or broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

About CUE-401
CUE-401 is a preclinical, bispecific fusion protein designed to induce and expand regulatory T cells (Tregs) through the delivery of transforming growth factor beta (TGF-β) and interleukin 2 (IL-2) with therapeutic potential across a range of T-cell mediated autoimmune and inflammatory diseases.

Cue Biopharma entered into a strategic collaboration and option agreement with Ono Pharmaceutical Co., Ltd. ("Ono") in February 2023 to support development of CUE-401.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* and biologics are designed to harness the body's intrinsic immune system as T cell engagers without the need for ex vivo manipulation or broad systemic modulation.

Headquartered in Boston, Massachusetts, we are led by an experienced management team and independent Board of Directors with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information please visit www.cuebiopharma.com and follow us on Twitter at https://twitter.com/CueBiopharma.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Such forward-looking statements include, but are not limited to, those regarding: the company's beliefs about the potential benefits of CUE-101 and the CUE 100 series; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; and the company's business strategies, plans and prospects. Forward-looking statements, which are based on certain assumptions and describe the company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or other comparable terms, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company's limited operating history, limited cash and a history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies, its ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including COVID-19, including possible effects on the company's trials; negative or inconclusive results from the company's clinical trials or preclinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; the Company's inability to replicate in later clinical trials any positive data demonstrated in earlier clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company's reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company's ability to obtain adequate financing to fund its business operations in the future; operations and clinical the company's ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the company's most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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